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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,428	11/30/2004	Francis Chi	505/9-2011	4964

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COLEMAN SUDOL SAPONE, P.C.  
714 COLORADO AVENUE  
BRIDGE PORT, CT 06605-1601

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/516,428	CHI ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,27,28 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-26 and 29-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/4/05</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Applicant's response received December 12, 2005 is acknowledged.

Claims 1-43 are pending in the instant application.

Applicant's election of Group III, claims 24-42 as they read on a method of administering anti-adipose tissue antibodies to modulate adipose tissue content, and the species of adipocyte plasma membranes in the reply filed on December 12, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 27 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in the reply filed on December 12, 2005 as explained above.

Claims 24-26 and 29-42 are under examination as they read on administering antibodies that bind adipocyte plasma membranes to modulate adipose tissue content.

### ***Claim Objections***

2. Claims 29-42 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP 608.01(n).

Claims 32, 35, and 41 are further objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Specifically, recitation of "different species" in claim 32 is broader than "distinctly different species" in claim 31, recitation of "closely related species" in claim 35 is broader than "same species" and "mammal" in claim 41 is broader than swine.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-26 and 29-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 24 and its dependent claims recite methods of modulating the content of adipose tissues by administering an antibody that binds the plasma membrane of adipocytes. The metes and bounds of the term "modulate" indicates that the recited methods can increase or decrease the content of adipose tissues. As such, it is unclear

what results a skilled artisan would have upon performing applicant's method as presently recited, and as such the claim is indefinite.

Claim 42 is further rejected because this claim recites the limitation "said animals" in line 2. There is insufficient antecedent basis for this limitation in the claim. This is because the prior claims recite multiple animals, such as target animals, source animals, and egg-laying animals. Since it is not clear which animal is being referenced as "said animal", the claim is indefinite.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 24-26 and 29-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of administering antibodies that bind adipocyte plasma membranes and decrease the amount of adipose tissue in an animal, does not reasonably provide enablement for methods of administering antibodies that bind adipocyte plasma membranes that modulate the amount of adipose tissue in an animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's claimed methods modulate adipose tissue content by administering an antibody that binds to the plasma membrane of adipocytes. In experiments II and III applicant has provided experimental evidence that administration of such antibodies to

an animal causes a reduction in the amount of adipose tissue in said animal. The scope of the term “modulating” does not appear to be explicitly defined by the specification, but recitation of this term can reasonably encompass methods of increasing as well as decreasing the amount of adipose tissue in an animal. No working examples appear to be present wherein the administered anti-adipocyte antibodies lead to an increase in the amount of adipose tissue mass, and the prior art of Flint (US Patent No. 5,102,658, of record as reference AB on the IDS received 3/4/05, see entire document) and Pimentel (US 2002/004045, of record as reference AA on the IDS received 3/4/05, see entire document) both indicate that administration of anti-adipocyte antibodies leads to a reduction in adipocyte tissues. Further, it is not clear from either applicant’s specification or from the prior art how administration of the same anti-adipocyte plasma membrane antibodies can have the diametrically opposite activities of increasing and decreasing adiposity in a target animal.

Therefore, based upon the breadth of the term “modulating”, the lack of a working example showing that the administered antibodies increase adipose tissues, the teachings of the prior art and applicant’s working examples showing that administration of anti-adipocyte antibodies leads to a reduction in adipose tissues, and the lack of teachings in the specification or prior art of how the same antibodies can have diametrically opposite activities when administered to a target animal, a skilled artisan would be unable to practice the full scope of applicant’s claimed method without first performing additional research.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24-26 and 29-42 are rejected under 35 U.S.C. 103(a) as being obvious over Flint (US Patent No. 5,102,658, of record as reference AB on the IDS received 3/4/05, see entire document) in view of Lee (US patent No. 5,367,054, see entire document).

Flint teaches a method of administering antibodies raised against adipocyte plasma membranes to target animals in order to decrease adipose tissue mass in the target animal (see entire document, particularly the abstract, claims 1-3, and lines 19-23 of column 1). He further teaches that the administered antibodies can be made in an animal that is evolutionarily removed from the target animal in which a decrease in adipose tissue is desired (see particularly lines 26-30 of column 1 and Example C). Note that in working example C, rats were administered anti-rat adipocyte plasma membrane polyclonal antibodies that had been made in sheep. Particularly desirable

target animals for the treatment methods taught by Flint include humans, lambs, cows, and pigs (see particularly lines 19-23 of column 1 and claim 3). The teachings of Flint differ from the instant claimed invention in that Flint does not specifically mention that egg laying animals are to be used to produce anti-adipocyte antibodies and Flint does not indicate that anti-adipocyte antibodies are to be orally administered.

Lee teaches methods of producing IgY antibodies from the yolk of chickens and other egg-laying animals such as reptiles, amphibians and fish (see entire document, particularly the abstract, lines 5-10 of column 1, and claims 1-15). Antibodies produced in eggs enjoy the advantages of increased specificity against mammalian proteins, low cost, convenience, and compatibility with animal welfare regulations (see particularly lines 34-47 of column 1). Additional advantages of egg yolk antibodies are that they can be easily administered in food and in other compositions suitable for oral ingestion (see particularly lines 29-33 of column 1 and lines 30-40 of column 3).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to administer anti-adipocyte plasma membrane antibodies to a target animal to reduce adipose tissue mass in the target animal as taught by Flint using anti-adipocyte plasma membrane antibodies produces in egg laying animals such as chickens as taught by Lee to gain the advantages of low cost antibodies that can be incorporated into food for increased ease of administration to patients as was also taught by Lee.


9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 6, 2006

  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600